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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,408	11/30/2006	Leander Grode	2923-737	4545

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
11/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/554,408	GRODE ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13July2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32 and 39-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-32* is/are allowed.

6)☒ Claim(s) *39-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/3/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Office Action, received 13 July 2009, is acknowledged. Claims 5, 39, 40, 42, 43 and 44 have been amended. New claim 47 has been added.

2. Claims 1-32 and 39-46 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for "stringent conditions", is withdrawn in light of the amendment of the claim.

Rejections Maintained

4. The rejection of claims 39-46 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained.

Applicants argue that the amendment of the claims to recite specific domains confers the capability to elicit an immune response to the specific disease state that one seeks to treat and that one of ordinary skill in the art would know which type of immune response to elicit to treat a given disease.

The examiner has considered applicants' arguments, in light of the claim amendments, but does not find them persuasive.

Newly amended claim 39 is remains a method of treating a mammal having a disease state, comprising administering to the mammal a bacterial cell which is urease-deficient and which comprises: 1) a recombinant nucleic acid molecule encoding a fusion polypeptide comprising ≥ 1 domain from a polypeptide selected from a group consisting of autoantigens, tumor antigens, virus antigens, parasite antigens, bacterial antigens and immunogenic fragments thereof, wherein said polypeptide domain is capable of eliciting "an" immune

response in a mammal, and, 2) a phagolysosomal escape domain, in a pharmaceutically effective amount.

According to this claim, one can utilize any of the listed polypeptide domains, regardless of source, to treat any disease state. The capability of the domain to elicit "an" immune response is not restricted to an immune response to the disease state, but can be any immune response.

Newly amended claim 40 is the method of claim 39, wherein the disease state is tuberculosis and the polypeptide domain is selected from the group consisting of mycobacterium antigens Ag85B (*M. tuberculosis*), Ag85B (*M. bovis*), Ag85A (*M. tuberculosis*), and ESAT-6 (*M. tuberculosis*) or an immunogenic fragment thereof. While the disease state is now confined to tuberculosis, there is no such restriction on the polypeptide domain when only a fragment of the listed antigens is utilized. Thus, the claim is a method of treating tuberculosis by utilizing any immunogenic polypeptide fragment of Ag85B (*M. tuberculosis*), Ag85B (*M. bovis*), Ag85A (*M. tuberculosis*), or ESAT-6 (*M. tuberculosis*).

Claim 41 is the method of claim 39, wherein the mammal is immunodeficient. As in claim 39, one can utilize any of the listed polypeptide domains, regardless of source, to treat any disease state. The capability of the domain to elicit "an" immune response is not restricted to an immune response to the disease state, but can be any immune response.

Newly amended claim 42 is the method of claim 41, wherein the disease state is HIV. While the disease state is now confined to HIV, there is no such restriction on the polypeptide domain of "a HIV antigen". Thus, the claim is a method of treating HIV by utilizing any polypeptide domain of any HIV antigen, regardless of whether the HIV antigen provides any treatment response.

Newly amended claim 43 is the method of claim 39 wherein said mammal has a tumor and the administration of said bacterial cell treats the tumor, wherein the domain capable of eliciting an immune response is "a" tumor antigen. There is no restriction on the polypeptide domain to have any relationship to said tumor. Thus, the claim is a method of treating tumor by utilizing any polypeptide domain from any tumor antigen, regardless of source.

Newly amended claim 44 is the method of claim 39 wherein the disease state is superficial bladder cancer. While the disease state is now confined to superficial bladder cancer and wherein the domain capable of eliciting an immune response is "a" tumor antigen, there is no such restriction on the polypeptide domain to have any relationship to superficial bladder cancer. Thus, the claim is a method of treating superficial bladder cancer by utilizing any polypeptide domain from any tumor antigen, regardless of source.

Claims 45 and 46 are identical to claim 39, except that said mammal is an animal or a human. As in claim 39, one can utilize any of the listed polypeptide domains, regardless of source, to treat any disease state. The capability of the domain to elicit "an" immune response is not restricted to an immune response to the disease state, but can be any immune response.

Therefor, the claims remain containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed method for treating any mammal having any disease state by administering a urease-deficient bacterial cell comprising a recombinant nucleic acid encoding for any polypeptide.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Newly added claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claim 47 is the method of claim 43, wherein the tumor antigen is selected from the group consisting of p53 tumor suppressor gene product, a melanocyte differentiation antigen, Melan-A/MART-1, and gp100.

There is no restriction on the polypeptide domain to have any relationship to said tumor. Thus, the claim is a method of treating any tumor by utilizing any polypeptide domain from any of the tumor antigens listed.

Conclusion

6. Claims 39 to 47 are rejected.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

November 19, 2009